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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/619,735	07/15/2003	Alton David Floyd	A-71601	7017

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EXAMINER

YU, MELANIE J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/619,735

Applicant(s)

FLOYD, ALTON DAVID

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,15,18,19 and 24-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,10-14 and 16-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of group I, claims 1-24, and the species of group A-epitope, group B-serum protein, group C-detection enzyme and group D-immuno-based assay, in the reply filed on 19 August 2006 is acknowledged.
2. Claims 8,9,15,18,19 and 24-46 have been withdrawn as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-7, 10-14, 16 and 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a plurality of control compounds immobilized at different sites, wherein each of the sites contains a different amount of one of the control compounds and claim 21 recites the plurality of quality control compounds comprising serum proteins, ligands, haptens and detection enzymes. It is unclear whether the serum proteins, ligands, haptens and detection enzymes are immobilized each immobilized at different sites or whether the compounds are immobilized at each site in different concentrations. It is vague as to whether all elements of serum proteins, ligands, haptens and detection enzymes are required as quality control compounds.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-7, 10-14, 16 and 20-23 are rejected under 35 USC 102(e) is anticipated by Bogen et al. (US 6,281,004).

Bogen et al. teach a device comprising: a plurality of quality control compounds, wherein each of the control compounds is reactive with one of said reagents used in the assay (different antigens immobilized to a support, col. 4, lines 22-28; plurality of assay locations, col. 3, lines 32-37); and a substrate wherein each of the control compounds is bound on a plurality of spatially defined sites on the substrate (col. 3, lines 32-37) and wherein each of the defined sites contains a different amount of one of the control compounds (col. 8, line 64 - col. 9, line 2; col. 9, lines 12-30).

With respect to claims 2-4, Bogen et al. teach the substrate being a matrix that is on a solid support that is a glass microscope slide and therefore the compounds are bound on the glass substrate (col. 13, lines 21-30; col. 5, lines 31-32).

Regarding claim 5, Bogen et al. teach the different amount being a serial dilution series of the control compound (col. 8, lines 64-67).

With respect to claims 6 and 11, Bogen et al. teach the quality control compounds reactive with a secondary reagent, that is not a primary reagent (antigens bind to antibodies which then bind to secondary antibodies, therefore the antigens indirectly bind to the secondary antibodies, col. 3, lines 32-51; col. 4, lines 5-14).

With respect to claim 7, Bogen et al. teach the plurality of quality control compounds comprising at least one ligand wherein one of the reagents is a binding partner of the ligand (col. 3, lines 32-51; col. 4, lines 5-14).

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Regarding claims 10 and 12-14, Bogen et al. teach the ligand comprising an epitope bound by an antibody (ligand is an antigen that binds to an antibody, col. 3, line 55-col. 4, line 4) that is a human serum protein (human IgG is a human serum protein, col. 10, lines 15-23).

With respect to claims 16 and 17, Bogen et al. teach the quality control compounds comprising at least one detection enzyme that is alkaline phosphatase (alkaline phosphatase is an enzyme used for colormetric development, col. 7, lines 21-23; a colormetric signal is detected from the quality control compounds on the substrate, col. 15, lines 6-18).

Regarding claim 20, Bogen et al. teach the device containing an identifying code (col. 7, lines 60-63).

With respect to claim 21, Bogen et al. teach the plurality of quality control compounds comprising serum proteins (human IgG is a human serum protein, col. 10, lines 15-23), ligands (different antigens immobilized to a support, col. 4, lines 22-28) and detection enzymes (col. 7, lines 21-23).

Regarding claims 22 and 23, Bogen et al. teach the assay comprising an immunohistochemical assay (col. 6, lines 35-41).

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

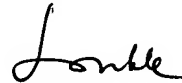
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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Art Unit 1641



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